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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,987	07/12/2001	Michael G. Douglas	42108/26146	3819

21888 7590 07/02/2003

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EXAMINER
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LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/904,987

Applicant(s)

DOUGLAS ET AL.

Examiner

Samuel W Liu

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-46 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-20, 22-36 and 38-46 is/are allowed.
- 6) ☒ Claim(s) 21 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

#### DETAILED ACTION

The response filed 9 May 2003 (Paper No. 9) as to cancellation of claims 1-17 and 47-48, and amendment of claims 18-46 have been entered. Thus, pending claims 18-46 are under examination to the extent that they are drawn to the elected invention.

Note that the grounds of objection and/or rejection not explicitly stated and/or set forth below are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Claim Rejections - 35 USC § 112*

The claim rejection under 35 U.S.C. 112, first paragraph, is withdrawn because the claim amendment in the response filed 9 May 2003 obviates the rejection.

Claim 21 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 37 recite "biologically active subunit"; the recitation is indefinite as the "subunit" refers to one of folded protein chains that constitute a quaternary protein (*i.e.*, each subunit is arranged in oligomer). Yet,  $\beta$ -amyloid is a monomeric protein (SEQ ID NO:1) not a protein having quaternary structure that is composed by subunits. The specification does not clearly define the recited "subunit". Thus, the recitation "...subunit" is indefinite.

Response to the rejection under 35 USC 112, the second paragraph

The response filed 9 May 2003 asserts that the specification has defined the term "subunit" which has the more broad definition than term *per se* subunit; thus, the response infers that the recitation "biologically active subunit" is not indefinite (see page 11, the second paragraph). The applicants' argument is not persuasive. The specification sets forth that the said subunit is a subunit of a peptide (see page 11, 6-9); such the definition for the subunit is not well understandable because (i) "peptide" refers to a biomolecule consisting of less than 50 amino acid residues being joined together in chains via peptide bonding (see the reference labeled REF 1) as opposed to the polypeptides recited in claims 21 and 37 that are of more than 100 residues; contrary to commonly accepted notion of peptide stated above, the specification definition as to the "a subunit of a peptide" is therefore improperly described and unclear, and (ii) "subunit", in biochemistry, is defined: two or more polypeptide chains that operate as a single, functional unit; each of the polypeptide chains is referred to as a *subunit* (see the reference labeled REF 2). The protein, not a peptide, of SEQ ID NO:1 (*i.e.*,  $\beta$ -amyloid) *per se* does not fall into a category of protein containing multiple polypeptide chains, *i.e.*, multiple subunits. Rather, this protein is monomeric protein. The recitation "biological active subunit" of  $\beta$ -amyloid protein is thus unclear regarding whether or not the recitation refers to chemically conjugated  $\beta$ -amyloid homodimer or homo-oligomer. Therefore, claims 21 ad 37 are deemed indefinite.

Moreover, since the current invention is directed to use of picolinic acid derivative compound for controlling protein assembly or aggregation mediated by conformational alteration thereof, it is necessary to distinguish between tertiary (a single polypeptide chain fold) and quaternary (assembly of multiple folded polypeptide chains) structures of protein. In light of this,

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therefore, required is the clarification of the recitation "biologically active subunit".

**Conclusion**

Claims 21 and 37 are rejected, and claims 18-20, 22-36, 38-46 are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER



Samuel Wei Liu, Ph.D.

June 19, 2003